

### **Remarks**

Claims 34 and 35 are amended and claim 36 is added. Claims 1-36 are pending.

In response to the Restriction Requirement mailed March 28, 2005, Applicant provisionally elects with traverse, the claims of Group V (claims 28-35) directed to an apparatus for analyzing test information including the level or amount of at least one protein in a sample obtained from a mammal, wherein the protein is selected from the group consisting of TGF- $\beta_1$ , IGFBP-2, IL-6, IL-6sR and IGFBP-3, so as to provide the risk of disease progression in the mammal or the risk of non-prostate confined disease in the mammal, and methods which employ software to analyze the test information. It is Applicant's position that new claim 36 should be assigned to Group V as it is directed to a nomogram in which test information including the level or amount of TGF- $\beta_1$ , IGFBP-2, IL-6, IL-6sR or IGFBP-3 in a sample from a patient is correlated to the risk of prostate disease progression in the patient or the risk of non-prostate confined disease in the patient. Reconsideration and withdrawal of the Restriction Requirement, in view of the remarks below, is respectfully requested.

The Restriction Requirement is traversed on the basis that the inventions are closely related. Claims directed to an apparatus for analyzing test information including the level or amount of at least one protein in a sample obtained from a mammal, wherein the protein is selected from the group consisting of TGF- $\beta_1$ , IGFBP-2, IL-6, IL-6sR and IGFBP-3, so as to provide the risk of disease progression in the mammal or the risk of non-prostate confined disease in the mammal, and methods which employ software to analyze the test information (claims 28-35; Group V) are clearly related to claims directed to methods of determining the risk of progression of a prostate cancer patient or the risk of non-prostate confined disease in a patient which detects or determines the amount or level of TGF-beta (claims 1-13, 15-10 and 22-25; Group I), claims directed to methods of determining the risk of progression of a prostate cancer patient or the risk of non-prostate confined disease in a patient which detects or determines the amount or level of IGFBP-2 (claims 1-13, 15-20 and 22-25; Group II), claims directed to methods of determining the risk of progression of a prostate cancer patient or the risk of non-prostate confined disease in a patient which detects or determines the amount or level of IGFBP-3 (claims 1-13, 15-20 and 22-25; Group III), and claims directed to methods of determining the

risk of progression of a prostate cancer patient or the risk of non-prostate confined disease in a patient which detects or determines the amount or level of IL-6 or IL6sR (claims 2-3, 5-19 and 21-25; Group IV).

The Restriction Requirement is also traversed on the basis that Restriction Requirements are optional in all cases. M.P.E.P. § 803. If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it arguably may include claims to distinct or independent inventions. M.P.E.P. § 803. Moreover, it is submitted that Applicant should not be required to incur the additional costs associated with the filing of multiple divisional applications in order to obtain protection for the claimed subject matter. For instance, due to the relatedness of the claims in Groups I-V, the claims in Groups I-V can be efficiently and effectively searched in a single search with no additional burden placed on the Examiner.

With regard to the Markush group of proteins recited in the elected claims, the Examiner is requested to consider that the group has utility to predict the outcome of prostate disease, and are proteins associated with cell growth that are found in the blood of a mammal. Moreover, as the members of the group are sufficiently few in number (5) and/or are closely related as described above, it is Applicant's position that unity of invention exists and so restriction of the Markush group is improper. M.P.E.P. 803.02. Accordingly, withdrawal of the restriction of the Markush group is respectfully requested.

Thus, the Restriction Requirement is properly traversed. Accordingly, reconsideration and withdrawal of the Restriction Requirement is respectfully requested

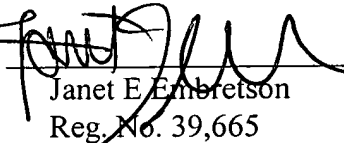
The Examiner is invited to telephone Applicant's attorney at (612) 373-6959 to facilitate prosecution of this application. If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

KEVIN M. SLAWIN ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
P.O. Box 2938  
Minneapolis, MN 55402  
(612) 373-6959

Date April 28, 2005 By   
Janet E. Embretson  
Reg. No. 39,665

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 28 day of April, 2005.

KACIA LEE  
Name

Kacia Lee  
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